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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,818	06/27/2003	Robert J. Sweeney	279.636US1	8382

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EXAMINER	
STOKLOSA, JOSEPH A	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
03/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/607,818	SWEENEY ET AL.	
	Examiner	Art Unit	
	JOSEPH STOKLOSA	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,25-27 and 58-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,25-27 and 58-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/1/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/1/2008 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-18, 25-27, and 58-61 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 1, 6, 13, 25, and 58 are vague and indefinite as to whether the controller actually takes the non-linear first and second derivatives, or if the curvatures just inherently are a nonlinear function of first and second derivatives, or if it requires that the curvatures simply be non-linear and have first and second derivatives. Examiner has interpreted Claims 1, 6, 13, 25, and 58 as the latter, and that as written the curvature series are inherently non-linear and have first and second derivatives.

5. Further, claim 1, contains the limitation "each associated with a time of a lobe in the curvature series..." Examiner considers this limitation to be vague and unclear as

whether the lobe is being calculated and all points along the curvature series inherently have a temporal relationship with some lobe of the curvature.

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-3, 6, 9, 13, 14, 17, 18, 25, 58, 59, and 60 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sweeney (US 4,996,984).

5. Sweeney discloses a defibrillation method involving determining a fibrillation cycle through the use of autocorrelation techniques (Col. 4, line 36-59). Examiner has interpreted the fundamental frequency claimed to be a mere manipulation of data that is obtained by Sweeney, since the fibrillation cycle would produce a period value and the fundamental frequency is equivalent to the inverse of the period as seen in the equation F = 1/T where T is the period. Although Sweeney is silent to the use of a memory coupled to the controller for determining the fundamental frequency through autocorrelation, Examiner considers this limitation to be inherently disclosed by Sweeney's invention as it would be impossible to perform the autocorrelation without at least some portion of the signal to be stored and accessed so that it could be correlated with itself.

6. Examiner also considers that each characteristic point (e.g. any sampled point of the signal) is associated with a time of a lobe in the curvature series (any series of individual points that make up a signal) as a function of the sampled signal. Examiner interprets this current limitation to only require that the series of sampled data points, which correspond to a time of a lobe because all points will correspond to a temporal lobe curvature. In other words a lobe in a signal is comprised of a series of points, any and all of which when sampled at an adequate frequency, will reproduce the frequency content of the lobe or if more sample points are take the entire signal.

7. It is also of note that the cardiac signal taken is non-linear and has first and second derivatives.

8. In the alternative it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Sweeney with use autocorrelation to determine a fundamental frequency of a cardiac signal, since autocorrelation is well known in the art to provide determination repeating features and the harmonics in signals and the fundamental frequency would provide the predictable result of allowing a cardioversion/defibrillating device to appropriately time delivery of stimulation. Further, it is well known in the signal processing art to sample the signal at an adequate frequency, abiding by at least Nyquist's theorem, to accurately reproduce a signal without loss of frequency content or aliasing. The frequency content in this particular case would be the lobe curvatures.

9. With regard to claim 2, the size of the characteristic point would inherently be used to determine the fibrillation cycle through the use of the autocorrelation function as disclosed by Sweeney, since it is known that by autocorrelating a signal the signals sampled points are compared to find the repeating signal pattern.

10. With regard to claim 3, Sweeney discloses determining the period length of a cardiac cycle. Examiner considers this to be a rate estimator because 1 cycle is equivalent to 1 heart beat. Further the term heart rate does not distinguish from the measured period length. In other words, if it is known that a cycle length is ~1 second, then a heart rate of 60 bpm is inherently known.

11. With regard to claim 14, Sweeney inherently teaches the autocorrelation of the signal in the time domain in that the signal is taken over a fixed time period (Col. 4, line 57).

12. With regard to claim 25 and 58, Examiner contends that Sweeney inherently discloses a machine accessible medium for accessing data to perform the disclosed method. The system must inherently posses a memory for accessing the autocorrelated signals as well as selecting and determining the defibrillating stimulation parameters.

13. In the alternative, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Sweeney with including an integral unit for storage and delivery of the cardiac signal analysis and defibrillation means since such a modification would provide the predictable results of an integral unit for reduction of space, power, and overall efficiency.

14. With regard to claim 60, Examiner considers Sweeney to establish a window before a characteristic point of the first series of characteristic points, since the sampling of the signal is done from some time interval $T_0 - T_1$ where the signal is sampled and the sampled points recreate the signal to be autocorrelated.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 4-5, 11-12, 15, 16, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney as applied above.

18. With regard to claim 4-5, Sweeney fails to teach the use of telemetry coupled to the controller communicating with a programmer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Sweeney, since such a modification would provide the predictable results of performing the signal processing externally and thereby reducing the size of power requirements of an implanted device.

19. With regard to claim12, Sweeney fails to explicitly discloses the autocorrelating parameters such as at least two factors being used from the characteristic points and finding a time overlap relationship. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Sweeney with the use of at least two factors being used from the characteristic points to autocorrelate the signal and finding a time overlap relationship, since such a modification would provide known autocorrelating techniques where multiple factors such as the amplitude of the signal or the timed relationship of the signal are used in the autocorrelating algorithm to provide the predictable results of accurate signal analysis and autocorrelation techniques.

20. With regard to claim 15, Sweeney discloses autocorrelating in the time domain, therefore it would also be obvious to one having ordinary skill in the art at the time the invention was made to autocorrelate the signal in the frequency domain, since it is known in the art that the frequency domain would provide the predictable results of providing the frequency spectra content of the signal as well as noise interference reduction.

21. Although Sweeney is silent to the electrical signal being a ventricular or atrial ECG, Sweeney does teach the monitoring of ventricular arrhythmias and therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Sweeney with monitoring a ventricular rate electrogram, counting either R waves (a first characteristic series point) or P-waves (a second series characteristic point series) for providing the predictable determining tachyarrhythmia so that the proper defibrillating treatment may be determined.

22. Claims 7-8, 10, and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney as applied above in view of Marcus (US 4,637,400).

23. Sweeney discloses the invention as claimed but fails to teach locating the center of a lobe and finding the area of the lobe to determine the frequency of the lobe. Marcus teaches that it is known to identify a lobe (Fig. 5A), calculating the area of the lobe (Col. 5, line 41-46; col. 6, line 10-17) for providing the predictable result of providing statistical data for the apparent differences in the visual curvatures observed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Sweeney with determining the area of the lobe from a

center of the lobe, for providing the predictable results of providing statistical data for the apparent differences in the visual curvatures observed.

Response to Arguments

24. Applicant's arguments with respect to claims 1-18, 25-27, 58-61 have been considered but are moot in view of the new ground(s) of rejection necessitated by Applicant's amendment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH STOKLOSA whose telephone number is (571)272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

Joseph Stoklosa
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2/23/2008